1.7.

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EXAMINER	
PRIOR, K	
ART UNIT	**PAPER NUMBER**
1209	11

DATE MAILED: 01/22/97

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☒ Responsive to communication filed on 24 Jan 96 & 26 Mar 96 ☒ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), — days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☐ Notice of References Cited by Examiner, PTO-892.
2. ☐ Notice of Draftsman's Patent Drawing Review, PTO-948.
3. ☐ Notice of Art Cited by Applicant, PTO-1449.
4. ☐ Notice of Informal Patent Application, PTO-152.
5. ☐ Information on How to Effect Drawing Changes, PTO-1474.
6. ☐ _____.

Part II SUMMARY OF ACTION

1. ☒ Claims 1 - 5 are pending in the application.
   Of the above, claims 3 are withdrawn from consideration.
2. ☐ Claims _____ have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☒ Claims 1-2 and 4-5 are rejected.
5. ☐ Claims _____ are objected to.
6. ☐ Claims _____ are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____. has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed _____, has been ☐ approved; ☐ disapproved (see explanation).
12. ☐ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____; filed on _____.
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

EXAMINER'S ACTION

First Action on the Merits of a File Wrapper Continuation

I. The election of Group I with traverse is acknowledged.

A. Restriction Requirement.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group I. Claims 1-2 and 4-5, drawn to compounds, compositions, & methods of use, classified in Class 540, subclass 108 and others.

Group II. Claim 3, drawn to a method of making compounds, classified in Class 552, subclass 569 and others.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product can be made by a diferent process such as formation of the 17-ester from the corresponding alcohol.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

B. Election of Species.

Claims 1-5 are generic to a plurality of disclosed patentably distinct species comprising the species of examples 1-61 and Tables 1-2. Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

C. Response.

During a telephone conversation with Glenn Murphy on 15 November 1996 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-2 and 4-5 and the species of Example 6. This is the same election made in the parent application Serial No. 08/310.791. Affirmation of this election must be made by applicant in responding to this Office action. Claim 3 has been

withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

D. Amendment of Inventorship.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

II. Claims 1 and 2 are objected to as being duplicates.

Claim 2 states that all other variables are the same as claim 1 and defines R^2 as a (C_1 -C_8)-alkyl, a phenyl, or a benzyl group. However, these are the only possibilities for R^2 in claim 1. Therefore, the claims describe the exact same genus of compounds. Upon either claim being found allowable the other will be rejected. *See* M.P.E.P. § 706.03(k).

III. The claims are rejected under 35 U.S.C. § 102(b).

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

A. Claims 1-2 and 4-5 are rejected under 35 U.S.C. § 102(b) as being anticipated by Villax, et al.

Claims 1-2 and 4-5 are rejected under 35 U.S.C. § 102(b) as being anticipated by Villax, et al.

Villax, et al teach 17,21-dicarboxylic esters having an aromatic group in the acid moiety attached at the 21 position. The reference specifically teaches the following compounds: 9-chloro-11,17,21-trihydroxy-16-methylpregna-1,4-diene-3,20-dione-17-acetate-21-benzoate; 9-chloro-11,17,21-trihydroxy-16-methylpregna-1,4-diene-3,20-dione-17-propionate-21-benzoate; 9-chloro-11,17,21-trihydroxy-16-methylpregna-1,4-diene-3,20-dione-17-butyrate-21-benzoate; and 9-chloro-11,17,21-trihydroxy-16-methylpregna-1,4-diene-3,20-dione-17-valerate-21-benzoate. (Col 4, lines 23-42) It also teaches that these compounds may be mixed with pharmaceutically acceptable excipients and applied topically to treat corticosteroid-responsive dermatoses. (Col 4, lns 48-62) These compounds, compositions, and methods taught be the reference are encompassed by the instant claims.

B. Claims 1-2 and 4-5 are rejected under 35 U.S.C. § 102(b) as being anticipated by Kamano, et al.

Claims 1-2 and 4-5 are rejected under 35 U.S.C. § 102(b) as being anticipated by Kamano, et al.

Kamano, et al teach 17,21-carboxylic esters and specifically teach the following compounds: 17-acetoxy-21-benzoyloxy-11-hydroxy-6-methyl-1,4-

pregnadiene-3,20-dione and 21-benzoyloxy-11-hydroxy-6-methyl-17-propionyloxy-1,4-pregnadiene-3,20-dione. (Col 9) The reference also teaches that the compounds can be formulated into compositions useful for the treatment of dermal disorders. (Col 8, lns 17-23 and 42-47) These compounds, compositions and methods are encompassed by the instant claims.

IV. The claims are rejected under 35 U.S.C. § 103(a).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

A. Claims 1-2 and 4-5 are rejected under 35 U.S.C. § 103(a) as being unpatentable over 1-2 and 4-5.

Claims 1-2 and 4-5 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Villax, et al.

Villax, et al teach 17,21-dicarboxylic esters having an aromatic group in the acid moiety attached at the 21 position. The reference specifically teaches the following compounds: 9-chloro-11,17,21-trihydroxy-16-methylpregna-1,4-diene-3,20-dione-17-acetate-21-benzoate; 9-chloro-11,17,21-trihydroxy-16-methylpregna-1,4-diene-3,20-dione-17-propionate-21-benzoate; 9-chloro-11,17,21-trihydroxy-16-methylpregna-1,4-diene-3,20-dione-17-butyrate-21-benzoate; and 9-chloro-11,17,21-trihydroxy-16-methylpregna-1,4-diene-3,20-dione-17-valerate-21-benzoate. (Col 4, lines 23-42) The reference also teaches that these compounds

may be mixed with pharmaceutically acceptable excipients and applied topically to treat corticosteroid-responsive dermatoses. (Col 4, lns 48-62)

The claims differ from the reference in that they include some compounds which contain differing halogens, methyl, etc. groups in the 6, 9, 11, and 16 positions. However, it is well known that compounds having a similar structure will have similar properties. Here the compounds are structurally similar because they are all 17,21-dicarboxylic ester-4-pregnen-3,20-diones having an optional double bound in the 1 and/or 9 positions or being substituted with similar groups in the 9, 11, and 16 positions. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to select any 17,21-dicarboxylic ester-4-pregnen-3,20-dione, including those of the instant claims, with the reasonable expectation that it would have the same use as the compounds of the reference, namely the treatment of dermatosis.

B. Claims 1-2 and 4-5 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Kamano, et al.

Claims 1-2 and 4-5 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Kamano, et al.

Kamano, et al teach 17,21-carboxylic esters and specifically teach the following compounds: 17-acetoxy-21-benzoyloxy-11-hydroxy-6-methyl-1,4-pregnadiene-3,20-dione and 21-benzoyloxy-11-hydroxy-6-methyl-17-propionyloxy-1,4-pregnadiene-3,20-dione. (Col 9) The reference also teaches that the compounds can be formulated into compositions useful for the treatment of dermal disorders. (Col 8, lns 17-23 and 42-47)

The claims differ from the reference in that they include some compounds which have a halogen or methyl group at the 6, 9, or 16 positions and have additional substituents at the 11 position. However, it is well known that

compounds having a similar structure will have similar properties. Here the compounds are structurally similar because they are all 17,21-dicarboxylic ester-1,4-pregnadien-3,20-diones. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to select any 17,21-dicarboxylic ester-4-pregnen-3,20-dione, including those of the instant claims, with the reasonable expectation that it would have the same use as the compounds of the reference, namely the treatment of dermal disorders.

C. Claims 1-2 and 4-5 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Annen, et al. ('451).

Claims 1-2 and 4-5 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Annen, et al. ('451).

Annen, et al. teach a 17,21-carboxylic ester-6,16-methyl-11-hydroxy-4-pregnen-3,20-dione optionally substituted in the 9-position and having an optional double bond in the 1-position. (See, Col 1,lns 15-42 of '451) The reference also teaches that the compounds can be used in pharmaceutical compositions for the treatment of various skin diseases. (Col 2, lns 10-29)

The claims differ from the reference in that they include some compounds which contain different groups in the 11 position. However, it is well known that compounds having a similar structure will have similar properties. Here the compounds are structurally similar because they are all 17,21-dicarboxylic ester-4-pregnen-6,16-methyl-3,20-diones having an optional double bound in the 1 position and having similar groups attached to the 9 position. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to select any 17,21-cicarboxylic ester-4-pregnen-6,16-methyl-3,20-dione, including those of the instant claims, with the reasonable expectation that it would have the same use as the compounds of the reference, namely the treatment of skin diseases.

Annen, et al. ('922 and '502) have not been applied in a rejection because they are cumulative the reference herein applied.

D. Claims 1-2 and 4-5 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Page, et al.

Claims 1-2 and 4-5 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Page, et al.

Page, et al. teach 17,21-dicarboxylic esters of 4-pregnen-3-20-dione having either an oxo or hydroxy group in the 11 position and having substituents similar to the instant claims in the 6, 9, and 16 positions. The compounds may also contain a double bound in the 1 position. (Col 1, lns 1-55) The reference also teaches the use of the compounds in pharmaceutical compositions for the treatment of corticosteroid-responsive dermatosis.

The claims differ from the reference in that they contain some additional compounds not taught by the reference, such as those having a 9(11) double bond. However, it is well known that compounds having a similar structure will have similar properties. Here the compounds are structurally similar because they are all 17,21-dicarboxylic ester-4-pregnen--3,20-diones having an optional double bound in the 1 position. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to select any 17,21-dicarboxylic ester-4-pregnen-6,16-methyl-3,20-dione, including those of the instant claims, with the reasonable expectation that it would have the same use as the compounds of the reference, namely the treatment of corticosteroid-responsive dermatosis.

EP 072,200 is has not been applied because it is cumulative of the reference herein applied.

E. Claims 1-2 and 4-5 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Annen, et al. ('763).

Claims 1-2 and 4-5 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Annen, et al. ('763).

Annen, et al. teaches 17,21-dicarboxylic esters in which the 17 and 21 positions are substituted with an acyloxy group. (Col. 1, lns 9-28) It also discloses the use of these compounds for the treatment of contact dermatitis. (Col 1, lns 52-59) The instant claims differ from the reference by reciting specific species in which the 21 acyloxy is a phenoyloxy or a benzoyloxy and the 17 acyloxy is either a C_{1-8}alkanoyloxy, a phenoyloxy, or a benzoyloxy. However, it would have been obvious to one having ordinary skill in the art at the time of the invention to select any of the species taught by the reference, including those of the claims, because an ordinary artisan would have the reasonable expectation that any of the species of a genus would have similar properties and, thus, the same use as the genus as a whole.

This is a file-wrapper-continuation of applicant's earlier application Serial No. 08/310,791. Each of the above rejections was made in Paper No. 7 in the parent application. The claims have not been amended, and the rejections have not been argued. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds or art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this

case. See M.P.E.P. § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kimberly J. Prior whose telephone number is (703) 308-4691. The examiner can normally be reached between 8 and 4. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, José Dees, can be reached on (703) 308-4628. The fax phone number for this Group is (703) 308-4556. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.

Kimberly J. Prior

Kimberly J. Prior
PRIMARY EXAMINER
ART UNIT 1209

KJP
18 January 1997